

REMARKS

Reconsideration of this application, in view of the amendment, is respectfully requested.

The Examiner requires restriction to one of ten grouped inventions under 35 U.S.C. § 121, as set forth and classified on pages 2 and 3 of the Office action, and then concludes that restriction for examination purposes is proper because these inventions are allegedly independent and distinct for reasons given on pages 3 and 4 of this action. An election of a single disclosed species is further required for reasons stated on pages 4 and 5 of the action.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement because the restriction is unwarranted under the circumstances. There is good reason to keep all of the claims in this single application. Equitable considerations also justify a withdrawal, or at least a significant modification, of the restriction requirement.

Despite the statutory classes, there is unity of invention that can be seen through the sole basis of the whole invention, namely, the novel methods of preparing the alpha-sulfonyl derivatives of the present invention in a more efficient manner than what is currently known in the art. For a thorough search, the Examiner will need to review the same literature involving the preparation of alpha-sulfonylhydroxamates repetitively for Groups I, II and IV-VI. The first search should suffice for a proper evaluation of all process claims.

Maintaining compound claims in the same application as the process for making them and their method of use is permissible and often done by the U.S. Patent and Trademark Office. There is no statutory prohibition against claims drawn to process, product and use residing in the same issued patent. Moreover, the Examiner has already done a significant search of the art and has taken action on the merits (for example, the rejections of Claims 1-53 under 35 U.S.C. § 112, first paragraph, and of Claims 39 and 45-47 under 35 U.S.C. § 103(a)) before Applicants have even made their election. Finalizing the search and considering the remaining subject matter of the claims will not place an unreasonable burden on the Office. There is ample justification, therefore, to keep Claims 1-53 in the same patent application.

In terms of equitable considerations, the restriction requirement effectively denies Applicants their substantive right to decide what they regard as their invention. By the Office's piecemeal approach to prosecution, Applicants would have to file and prosecute a total of ten applications at great time and expense to issue and maintain ten separate patents. Practically

speaking, it is not likely that Applicants would be able to take that expensive route. The restriction requirement, as it now stands, will effectively and unfairly force the Applicants to forfeit patent coverage of many important aspects of their invention. The substantial cost benefit of keeping this application intact is combined with the belief that performing the searches at the same time will not involve an undue or unreasonable burden on the part of the Office. If anything, the searches will overlap with common subject matter, the scope of several searches will ultimately be the same and the Examiner will replicate his efforts many times over. Thus, Applicants urge the Examiner to withdraw the requirement to restrict this application or, at the very least, to modify the overwhelming number of groups.

Consistent with the foregoing remarks and in accordance with the requirement of 37 C.F.R. § 1.143, Applicants provisionally elect with traverse to prosecute the invention of Group I, Claims 1-14, drawn to a method of preparing alpha-sulfonyl derivatives of formula V using a carbonyl intermediate of formula IV. Further, Applicants provisionally elect with traverse the single disclosed compound species from Example 36, (4-[4-(4-chlorophenoxy)-benzenesulfonyl]-1-benzyl-piperidine-4-carboxylic acid hydroxyamide hydrochloride).

It is respectfully asked, nevertheless, that the Examiner seriously consider modifying the restriction requirement to combine the subject matter of Claims 29-44 and 53 (Group II in part, Groups II-VI, Group X in part) with Group I because Claims 29-39 and 53 are ultimately dependent upon Claim 1 and Claims 40-44 specify the method of Claim 1 for the piperidine ring system structure IA. Claim 39 applies the method of Claim 1 to structure IA and then Claims 40 - 44 specify each of the steps of the method of Claim 1 for this structure. The steps and reagents are the same in Claim 1 and Claims 40-44, *i.e.*, deprotonation alpha to the ester followed by treatment with a sulfonyl fluoride.

It is also requested that the Examiner reconsider keeping the process of Group II, drawn to Claims 15-28, in this case. Once he has reviewed the process art for making the compound of formula V in Group I, he can proceed without undue burden to evaluate the patentability of the process of Group II, which makes the same compound of formula V.

Applicants currently retain the nonelected subject matter to afford the Examiner the opportunity to reconsider the restriction requirement and, thus, for future consideration on the merits. It is to be understood that the provisional election is for procedural purposes only and

that Applicants reserve the right to file a divisional application directed to the nonelected subject matter of this invention or a petition to modify the restriction requirement in the event that the restriction requirement is upheld.

The Examiner rejects Claims 39 and 45-47 under 35 U.S.C. § 103(a) as being unpatentable over Barta *et al.* (WO 00/71514) for reasons stated on page 6 of the Office action. Applicants respectfully traverse this rejection for the following reasons.

Insofar as Claim 39 is concerned, it is assumed that the Examiner acted under the wrong presumption that the claim is drawn to a compound. The present amendment makes it clear that the claim is a method claim drawn to a process for making the compound. Consequently, the amendment would overcome the obviousness rejection of Claim 39.

Regarding Claims 45-47, the compounds disclosed in Barta *et al.* differ from the compounds of the present invention in two significant respects. The Barta *et al.* reference is restricted to alpha amino acids and to structures where the sulfonyl group is beta to the carbonyl. In Claims 45-47, the sulfonyl group is alpha to the carbonyl and the nitrogen is beta. Also, looking at the Barta *et al.* reference, the generic structure does not have any provision for the nitrogen being in a ring that includes the carbon alpha to the carbonyl. On close scrutiny of the examples and claims of the reference, it is clear that Barta *et al.* do not describe or name any compound remotely similar to Applicants' compound of Formula IX. If anything, the reference teaches away from Formula IX. Thus, the present invention is not rendered obvious from the reference.

In view of the foregoing remarks, Applicants respectfully request that the rejection of Claims 39 and 45-47 under 35 U.S.C. § 103(a) be withdrawn. Alternatively, it is submitted that the Examiner should consider removing Barta *et al.* as a prior art reference since the foreign document was published on November 30, 2000, after the present application was effectively filed in the U.S. Patent and Trademark Office on January 27, 2000 (the filing date of the prior provisional application).

The Examiner rejects Claims 1-53 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. For reasons set forth on pages 7 and 8 of the application, the Examiner asserts that heterocyclic

substituted derivatives, other than where R₁ and R₂ form a piperidine ring, are not enabled by the specification. Applicants respectfully traverse this rejection for the following reasons.

The test of enablement is whether the specification contains an adequate disclosure of the claimed invention to enable the ordinary practitioner to make and use the invention without undue experimentation. It has been well established that claims do not need to be limited to the exemplification in the specification. In fact, working examples are not even a statutory requirement (*Ex parte Nardi and Simier*, 229 U.S.P.Q. 79 (B.P.A.I. 1986)).

In the present case, one of ordinary skill in the relevant art would be able to prepare all of the heterocyclic substituted derivatives of the claimed invention without undue effort. The process of making these compounds would be clear and routine to the ordinary chemist based on the guidelines illustrated in the application for the representative alpha-sulfonyl hydroxamic acid derivatives in light of current chemical literature such as, for example, the ACD (available chemical database that shows thousands of esters, alcohols and acids), standard textbooks on organic synthesis and other widely available resources. It is clear that the ordinary chemist would be able to make any of the claimed compounds without undue experimentation. Consequently, the specification satisfies the test of enablement.

In view of the foregoing remarks, Applicants respectfully request that the rejection of Claims 1-53 under 35 U.S.C. § 112, first paragraph, be withdrawn. Accordingly, it is requested that the application be allowed in its entirety. Favorable treatment is respectfully solicited.

Respectfully submitted,

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Date: June 3, 2003

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FILING BY EXPRESS MAIL UNDER 37 C.F.R. § 1.10

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